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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,873	12/06/2004	Hilmar Meek Warenius	185737/US	1109

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EXAMINER	
PHAM, AUDREY S	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/508,873	WARENIUS ET AL.	
	Examiner	Art Unit	
	Audrey S. Pham	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15, 18-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Warenius, *et al.*

Claims 1-24 were pending.

Claims 16-17 have been canceled.

Claims 25-28 are newly added.

Claims 1-15, 18-28 are currently under consideration.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Claims 1-8, drawn specifically to a method of screening for an agent effective in the treatment of cancer, which method comprises selecting a putative agent, treating a cancer cell sample and a control cell sample with the putative agent and determining the growth inhibiting effect of the putative agent, and identifying an effective agent as an agent which is more inhibiting to the growth of the cancer cell sample than the control sample

2. Claims 1-8, drawn specifically to a method of screening for an agent effective in the treatment of cancer, which method comprises selecting a putative agent, treating a cancer cell sample and a control cell sample with the putative agent and determining the cytotoxic effect of the putative agent, and identifying an

effective agent as an agent which is more cytotoxic to the growth of the cancer cell sample than the control sample

3. Claims 9-10, drawn to a method for screening an agent effective in preventing a cancer from undergoing metastasis, which method comprises selecting a putative agent, determining the ability of the sample of metastatic cancer cells to undergo metastasis and identifying an effective agent as an agent which reduces the ability of said sample, wherein said agent is a peptide or protein.

4. Claims 11-12, 14, 22 drawn to an agent, a pharmaceutical composition and a kit thereof, for use in medicine, which agent is capable of disrupting a function of a critical normal gene product which function is required for the successful division and continued cell survival, wherein the agent is an antisense oligonucleotide having the sequence SEQ ID NO: 2.

5. Claims 13, 23, 25 drawn to an agent, a pharmaceutical composition and a kit thereof for use in medicine, which agent is capable of disrupting a function of a critical normal gene product for metastasis in such a manner as to reduce the ability of a metastatic cancer cell in a sample to metastasized.

6. Claims 15, 26, drawn to a method of manufacturing a pharmaceutical composition, which method comprises identifying an effective agent according to the screening method and manufacturing a pharmaceutical composition comprising said effective agent in the treatment of a cancer.

7. Claims 18, 20, drawn to a method of treating a patient having cancer comprising identifying a critical normal gene product and treating the patient with an agent capable of disrupting a function wherein the agent is an antisense oligonucleotide having the sequence set out in SEQ ID NO: 2.

8. Claims 19, 21, 28, drawn to a method of treating a patient having metastatic cancer comprising identifying a critical normal gene product for metastasis present in said cancer and treating the patient with an agent wherein the agent is an agent capable of disrupting a function of a critical normal gene product for

metastasis in such a manner as to reduce the ability of a metastatic cancer cell in a sample.

9. Claim 24, drawn to a method for identifying a critical normal gene product, which method comprises detection of a gene product in L23COR cells that are quiescent or proliferating, detecting of said gene product and identifying a critical normal gene product as a gene product which is present at higher levels in quiescent or proliferating L23COR cells than in dying L23COR cells.

10. Claim 27, drawn to a method of manufacturing a pharmaceutical composition, which method comprises identifying an effective agent according to the screening method for an agent effective in preventing cancer.

Rule 13.1 of the Patent Cooperation Treaty (PCT) states that an international application should relate to only one invention or to a group of inventions if all inventions are so linked as to form a single inventive concept; *i.e.*, if there is unity of invention. According to Rule 13.2, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The term "special technical features" is referred to as those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art (Rule 13.2). The determination is made on the contents of the claims as interpreted in light of the description and drawing (if any). If there is special technical feature and/or if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as groups 1-10 do not relate to a single general inventive concept as required under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons

The technical feature linking groups 1-10 appears to be an agent capable of disrupting a function of a critical normal gene product.

However, said technical feature does not constitute a special technical feature in view of the international search authority's citing of several references that render the claimed invention to lack novelty, i.e. "X" references in the corresponding PCT (PCT/GB03/01275) application. For example, the X reference Yamamoto *et al.* (*Clinical Cancer Research*, July 1999, Vol. 5, No. 7, pages 1805-1818) were applied against claims 1-15, 18-23, drawn to a method for examining the phenotypic effect (i.e., screening) an antisense oligodeoxynucleotide (i.e., agent) targeting a tumor suppressor retinoblastoma (Rb) gene, which plays a key role as a negative regulator of the G1 to S transition in the cell cycle (i.e., a function mediated by a critical normal gene product) by treating the HCT116 colon carcinoma cell line and normal human colorectal mucosa and identifying the antisense oligodeoxynucleotide as a growth inhibitor (abstract, page 1805 col 2 para 2). Therefore, the technical feature linking the inventions of groups 1-10 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, groups 1-10 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept and restriction for examination purposes as indicated is proper.

Species Election

One or more of the above invention groups each contains multiple generic claims that include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility (*See In re Harnisch*, 631 F. 2d 716, 206 USPQ 300 (CCPA 1980) and MPEP § 803.02). Because they are not so closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Groups 1-2 are generic to a plurality of disclosed patentably distinct species comprising the following **factors**: *which impedes progress through the cell cycle, an anti-apoptotic factor, and a master regulatory gene product which regulates the levels of other gene products involved in the cell cycle and apoptosis pathways* (recited in Claim 2). The above species

represent separate and distinct factors with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Groups 1-2 are generic to a plurality of disclosed patentably distinct species comprising the following **agents**: *an agent capable of altering the ratio levels of the CDK1 and CDK4 gene product in a cancer cell sample* (Claim 4) *and an agent which is capable of reducing the levels of the CDK1 and CDK4 gene products below those observed in the untreated cancer cell sample* (Claim 6). The above species represent separate and distinct agents that differ at least in etiology, pathology, and mechanisms. As such, each species would require different searches and the consideration of different patentability issues.

Groups 1-3 are generic to a plurality of disclosed patentably distinct species comprising the following **critical normal gene products**: *and a human CDK4* (Claim 7), *a protease* (Claim 10), *a protein associated with cell division* (Claim 10), *a protein associated with motility* (Claim 10), *a master regulatory gene product which regulates the levels of gene products involved in all aspects of carcinogenesis* (Claim 10). The above species represent separate and distinct critical normal gene products with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Upon election of group 1, 2 or 3, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoining Claims

The Examiner has required restriction between product and process claims. Where Applicant elects claim(s) directed to a product and the product claim(s) is/are subsequently found allowable, the withdrawn process claim(s) that depend(s) from or otherwise include all the limitations of the allowable product claim(s) will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if an amendment is presented prior to a final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendment submitted after allowance is governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claim(s) and process claim(s) may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the withdrawn process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Amendment

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The Examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Audrey S. Pham
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JEFFREY SIEW
SUPERVISORY PATENT EXAMINER